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Regulatory Directive DIR2013-01

Revised Management of Submissions Policy

This document consolidates the performance standards and describes the process for managing submissions.

(publié aussi en français)

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1.0 Purpose

Pursuant to the *Pest Control Products Act*, no person can manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the Act or unless specifically exempted by the Pest Control Products Regulations.

The purpose of this document is two-fold:

- To communicate the Revised Management of Submissions Policy (MOSP) processes. Theses revisions were consulted on via the Regulatory Proposal PRO2010-05 *Revised Management of Submissions Policy* and replace the submission management processes documented in Regulatory Proposal PRO96-01, *Management of Submissions Policy*.

- To consolidate into one place the current performance timelines for managing applications submitted to Health Canada's Pest Management Regulatory Agency (PMRA).

The revisions will result in a submission management process that is more efficient, effective, and predictable for applicants/registrants and the PMRA. The expected result will be a closer alignment of the management of submissions with approaches used by regulatory authorities in other jurisdictions, which will facilitate work-share and joint review of applications with other jurisdictions.

2.0 Implementation

As of the date of publication, the Revised MOSP processes described in this document apply to all submission categories, as outlined in Section 3.0 Scope, received for the first time by the PMRA.

2.1 Category A and B submissions currently with the PMRA at the Completeness Check Stage: All Category A and B submissions that are in the Completeness Check stage on the date of publication will follow the processes described in this document. A bilingual label in MS Word format will now be a data requirement of the Completeness Check Stage and the PMRA will issue a request for a bilingual label if one was not received as part of the application package.

2.2 Category A and B submissions currently with the PMRA at the Review Stage: Category A and B submissions that are in the Review Stage on the date of publication will continue to follow the processes documented in Regulatory Proposal PRO96-01, *Management of Submissions Policy*; however, a limited transition to the Revised MOSP applies to these submissions.

Specifically:

- Notice of Deficiencies are managed as outlined in this document.
- There will be no 45-day Second Screening Stage as outlined in the Regulatory Proposal PRO96-01, rather the Second Review Stage commences once an adequate response is received.
- The Label Review process described in this document will apply, and a bilingual label will be requested if one was not received as part of the application package.

3.0 Scope

This document pertains to all applications for:

- the registration or amendment of a pest control product,
- the specification of a maximum residue limit (MRL),
- the authorisation or notification of research,
- the issuance of an equivalency certificate and authorisation of importation for own use, and
- the conduct of presubmission consultations and examination of submissions under the User Requested Minor Use Label Expansion (URMULE) Programme.

The same general process applies to all categories of submissions. However, some steps are not required for all categories. Depending on the purpose of the application and the type of information required, every submission subject to the MOSP is assigned to one of the five following categories:

Category A

- New active ingredients or integrated system products, their related end-use products, and manufacturing-use products
- Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient)
- Specification of import MRLs for an unregistered active ingredient

Category B

- New pest control products containing registered active ingredients
- Amendment to existing pest control products (for example, product chemistry, labelling)
- Conversion or renewal of conditional registration
- Emergency registration
- The addition of import MRLs for previously assessed active ingredients

Category C

- Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products.

Category D

- Submissions within particular programs including:
  - Import for Manufacture and Export Program (IMEP),
  - Own Use Import (OUI),
  - Grower Requested Own Use (GROU) Equivalency and import permits,
  - User Requested Minor Use Label Expansion (URMULE),
  - Registration Renewal, and
  - Discontinuations.

Category E

- Research authorisations for new active ingredients and new use(s) of registered active ingredients
- Research notification for research carried out in Canada

4.0 Instructions for Submitting an Application

Various guidance documents are available on the Pesticides and Pest Management portion of Heath Canada's website to help applicants prepare a complete application package. Instructions on submitting information for registration can be found in Regulatory Directive DIR2006-05, *Requirements for Submitting Data Index, Documents and Forms.*

5.0 The Revised Management of Submissions Policy Process

The following sections provide a step-by-step description of the submission review process according to the Revised MOSP.

Under the Revised MOSP, applications are typically reviewed in chronological order within each MOSP category subdivision. However, under certain circumstances timelines may be adjusted:

- If there is a critical need, an expedited review[1] may be considered. The intent of expedited reviews is to meet the urgent needs of users of pest control products, to facilitate risk reduction or to address a public health or environmental concern. For example, to replace an active ingredient being phased out through re-evaluation, a formulation amendment to replace a formulant of concern, or products needed to mitigate a public health or environmental risk.

- Related submissions may be grouped in order to follow the same review timeline. The grouping of related submissions occurs when one submission depends upon the success of the other. For example, an end use product cannot be registered before the technical active ingredient is registered and conversely, an active ingredient must have a use associated with it to be registered.

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[1] Prior to considering an adjustment to a submission timeline for an expedited review the PMRA must have ascertained that the submission has a complete and reviewable data package.

The Revised MOSP performance timelines in calendar days are summarized in Appendix I, Tables 1 to 5 (for Categories A to E, respectively). Note: Within each category there are further subdivisions (for example, submission subcategories, submission types, classes) that may have shorter performance timelines because they are conducted under specific programs (for example, Joint Review).

A submission flow diagram is depicted in Appendix II to illustrate the MOSP examination process for a standard Category A submission. Note: other categories will follow the same process using the performance timelines provided in Appendix I. However, some steps will not apply to every submission category and/or submission subdivision (for example, public consultation is not required for Category C submission decisions).

5.1 Completeness Check (Verification and Screening)

A completeness check will be performed on all submissions to ensure a complete submission has been received before the review stage is started. The performance timelines for the completeness check are outlined in Appendix I. When the submission is received by the PMRA, the completeness check clock will start. The completeness check will generally consist of an initial verification step and a more detailed screening step.

5.1.1 Verification

For most submission categories there is a seven-calendar-day verification step during which submissions are verified to ensure that non-data elements have been provided. Non-data elements may include the covering letter, the appropriate application form, the Statement of Product Specification Form, the Fee Form, the fee and the e-index. A submission found to be deficient at the verification step will result in an e-mail, outlining the deficiencies, being sent to the applicant and the submission being placed "on-hold". The applicant is given 14 calendar days to address the deficiencies. When a response is received from the applicant, a second verification period of a maximum of seven calendar days will apply and the completeness check clock will be reset to day 0. Lack of an adequate response will result in the submission being rejected.

Applicants are provided a submission number acknowledging receipt of the submission. This number should appear on all subsequent correspondence to the Agency relating to that submission.

5.1.2 Screening

For most submission categories there is a 30-calendar-day screening step during which submissions are screened to ensure they meet the format, data and fee requirements of the PMRA before they are accepted for review.

Clarifications
The PMRA may request minor clarifications concerning submitted information by e-mail or facsimile (for example, clarification of the Statement of Product Specification Form). The applicant has 10 calendar days to respond to the clarification request; screening continues during

this time. If an adequate response to the request for clarification is not provided within the timeframe specified, a Notice of Deficiencies will be issued. A Notice of Deficiencies can also be sent to the applicant when significant deficiencies are identified during screening.
Note: Clarifications may also be sent out during the review stage–refer to Section 5.2.

Notice of Deficiencies
During the screening stage, the PMRA will place a submission "on-hold" if deficiencies are identified in the application requirements or if insufficient information has been submitted (for example, if required test data is missing). Note: deficiencies may also be identified during the review stage; refer to Section 5.2.

When a Notice of Deficiencies is issued at screening (at which time the completeness check clock stops), the applicant must respond to the Notice of Deficiencies within the timeframe specified in the notice, usually 45 calendar days, and provide all of the requested information as directed. (Note: When one submission in a group of related submissions is put "on-hold", all of the related submissions will also be put "on-hold"). When a response to the Notice of Deficiencies is received by the PMRA, the completeness check clock will be reset with 15 calendar days on the clock.

No reminders will be issued. If there is no response or if the response is incomplete or inadequate, the application will be denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application. Any submission that has been previously withdrawn by the applicant, or denied by the PMRA during a previous examination, may be re-submitted at a future date. It will be considered a new submission and assigned a new submission number.

5.2 Review Stage

The review stage includes the following activities:

- Science evaluation of the health and environmental risks and the value of the pest control product to determine if they are acceptable
- The review of the bilingual product label
- The decision-making process

The review times outlined in Appendix I are in calendar days allotted to the PMRA to conduct all of the steps in the review stage. Note: If related submissions have different review timelines, the longer review timeline will usually apply to all of the submissions in the group.

The review stage clock will start as soon as the completeness check is completed. Excluded from the review time is the 45-calendar-day public consultation period for major regulatory decisions (for example, new active ingredients and major new uses) and for conversion/renewal of conditional registrations, both conducted via the publication of a Proposed Registration Decision.

5.2.1 Science Evaluation

The PMRA may request clarifications of minor points on submitted data by e-mail or facsimile. The applicant has 10 calendar days to respond to the clarification request; the review continues during this time. If an adequate response to the request for clarification is not provided within the 10 calendar days, a Notice of Deficiencies will be issued, the submission will be placed "on-hold", and the review stage clock will stop. Note: As indicated previously, when one submission in a group of related submissions is placed "on-hold", all related submissions will also be put "on-hold".

If deficiencies are identified by a single science review stream at any time during the review stage, a Notice of Deficiencies will be sent to the applicant, the submission will be placed "on-hold", and the review stage clock will stop. The science review stream to which the deficiencies apply will stop that portion of the review; however, the remaining science review streams will continue to actively work on the submission during this time if this is possible, and determined to be efficient. The applicant is given a specified number of days (usually 90 calendar days) to fulfil the requirements outlined in the Notice of Deficiencies. There will be no reminders provided during the "on-hold" period. When the response is received within the required timeframe, the review stage clock will immediately restart and the affected science review stream will continue their review. Lack of a response within the required time frame will result in the application being denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the submission.

The PMRA will issue one consolidated Notice of Deficiencies to the extent possible; however, in the event that deficiencies are identified by a second science review stream during the course of the first "on-hold", a second Notice of Deficiencies will be sent to the applicant and the review stage clock will remain stopped. The applicant will be given a specified number of days (usually 90 calendar days) from the time of the second Notice of Deficiencies to fulfil the identified data requirements. This new timeline will serve as the timeline for receipt of all data. Upon receipt of a response to a Notice of Deficiencies the science review stream for whom the deficiencies have been addressed will resume review of the submission; however, the review stage clock will remain "on-hold" if any Notices of Deficiencies remain outstanding, and the review will remain stopped for any science review stream for whom a Notice of Deficiencies remains outstanding. The review stage clock will not resume until such time that a response to all outstanding Notices of Deficiencies has been received by the PMRA.

5.2.2 Label Review

To facilitate timely issuance of the approved product label, a bilingual proposed product label must be submitted with the application. Provided the proposed product label is acceptable, the label review continues throughout the review process and the PMRA will make necessary label revisions to the proposed product label. Should extensive changes be required to the proposed product label the PMRA will request the applicant to make changes and provide an updated proposed product label during the review process. Translation of label revisions resulting from the science evaluation will be provided by the PMRA.

The PMRA will communicate to the applicant any changes resulting from the science evaluation before finalizing the product label. This will provide an opportunity for the applicant to clarify issues arising from the label revisions.

5.2.3 Decision

If there is sufficient scientific evidence to show that a product does not pose unacceptable health or environmental risks and that it has value, a decision to issue an authorisation (i.e. permit) or register the product will be made. The applicant will receive a decision letter and at the same time, if applicable, the PMRA will issue the approved bilingual label and the certificate of registration.

5.3 Public Consultation

A bilingual consultation document (Proposed Registration Decision) is published for all major decisions (for example, new active ingredients and major new uses of registered pesticides) as defined under subsection 28(1) *Pest Control Products Act*, unless the requirement to consult the public is postponed under paragraph 14(1)(*b*) of the Pest Control Products Regulations as a result of a conditional registration.

The consultation period for all Proposed Registration Decisions is 45 days from the date of publication. The comments received during the consultation period are considered before rendering the final regulatory decision.

5.3.1 Conditional Registration

Applications for renewal of a conditional registration or for conversion to a full registration, upon the fulfilment of conditions specified in a Section 12 notice, are treated as a Category B submission. Public consultation under subsection 28(1) of the *Pest Control Products Act* is required for all cases where consultation was postponed for a major decision under paragraph 14(1)(*b*) of the Pest Control Products Regulations.

5.4 Renegotiation of Review Timelines

Review times as detailed in Appendix I may need to be renegotiated by the PMRA and the applicant for the purpose of synchronizing the reviews of related submissions, or to allow for the review of additional information required to make a regulatory decision.

5.5 Measures

Completeness Check Time
The time taken from initial receipt of an application (or from when a response to a verification deficiency is received) to the end of the first screening.

Review Time
The time after the completeness check is completed to when a final regulatory decision is made, excluding applicant time (when a submission is placed "on-hold" pending an applicant response to a Notice of Deficiencies) and excluding public consultation time.

Applicant Time
The time when a submission is pending an applicant to respond to a Notice of Deficiencies, in other words, when the completeness check or review clocks are "on-hold".

Total Time
From the date that an application is received to the date that the submission is registered, rejected, withdrawn, denied or completed.

Performance Standard
The PMRA's performance standard is that 90% of submissions in all categories are to be processed within the applicable review timelines.

5.6 Dispute Resolution

To minimize disputes, applicants are encouraged to familiarize themselves with the pesticide registration process and registration requirements and to request, when appropriate, a presubmission consultation.

The PMRA will make every effort to manage and resolve disputes at the organizational level at which they take place.

Disputes regarding the screening of an application, including: screening deficiencies, data requirements, screening timeline, should be addressed to the screening officer assigned to the submission.

Disputes regarding the review of the submission, including: review deficiencies, data requirements, review timeline, labelling revisions and review decision, should be addressed to the administrative coordinator assigned to the submission.

If mechanisms for early dispute resolution fail, applicants should contact the Chief Registrar's Office of the PMRA. For major regulatory decision proposals, there is an opportunity for the applicant (or any member of the public) to comment during the public consultation period. In addition, for any major regulatory decisions for which a public consultation under section 28(1) of the *Pest Control Products Act* was required before a regulatory decision was taken, the applicant (or any member of the public) has another opportunity to comment by filing a Notice of Objection requesting the reconsideration of the decision within 60 days after the decision is made public.

For additional information on the reconsideration of decision process, please consult the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the Health Canada PMRA's Pest Management Information Service.

Appendix I Revised MOSP Performance Timelines for Pest Control Product Applications

(Performance Standard = 90% of submissions to be processed within the applicable review timelines)

Table 1 Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, new MRLs and major new use registration)

Category Subdivision	Completeness Check in Days	Review Time in Days (Months)*	Public Consultation in Days
Conventional chemical	37	655 (22)	45
Reduced-risk**, other biopesticides, NSCLP***	37	555 (18.5)	45
Microbials	37	470 (15.5)	45
Pheromones – SCLP****	37	285 (9.5)	45
Joint reviews	37	negotiated	45
URMUR	37	470 (15.5)	45
URMUR – SCLP****	37	285 (9.5)	45
Program 914	37	negotiated (<470 days)	45
Import MRL*****	37	655 (22)	n/a

* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes:
- a 45-day public consultation period if applicable
- time when a submission is "on-hold" pending the applicant

** Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

*** Non Straight Chain Lepidopteran Pheromone

**** Straight Chain Lepidopteran Pheromone

***** Maximum Residue Limit

Table 2 Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, renewal or conversion of conditional registration, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application)

Category Subdivision	Completeness Check in Days	Review Time in Days (months)*	Public Consultation in Days
Conventional chemical	37	425 (14)	n/a
Streamlined (application rate changes, tank mixes, new pests or changes to level of control)	37	158 (5)	n/a
Reduced-risk**, other biopesticides, NSCLP***	37	360 (12)	n/a
Renewal or conversion of conditional registration (with public consultation)*****	37	470 (15.5)	45
Renewal or conversion of conditional registration (without public consultation)*****	37	425 (14)	n/a
Microbials	37	240 (8)	n/a
Pheromones – SCLP****	37	240 (8)	n/a
New MRL for previously assessed active ingredient*****	37	425 (14)	n/a
Emergency use (priority): Reduced-risk**, other biopesticides, NSCLP***	37	<360 (12)	n/a
Emergency use (priority): Conventional chemicals	37	<425 (14)	n/a
Joint review	37	negotiated	n/a

* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes:
- a 45-day public consultation period if applicable
- time when a submission is "on-hold" pending the applicant

** Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*

*** Non Straight Chain Lepidopteran Pheromone

**** Straight Chain Lepidopteran Pheromone

***** Maximum Residue Limit

Table 3 Category C Submission Performance Timelines in Number of Calendar Days (includes changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, administrative changes or re-instatements)

Category Subdivision	Completeness Check Time in Days	Review Time in days (months)*
Standard	37	240 (8)

* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes: time when a submission is "on-hold" pending the applicant .

Table 4 Category D Submission and Presubmission Performance Timelines in Number of Calendar Days

Category Subdivision	Completeness Check Time in Days	Review Time in Days*
IMEP	21	46
OUI equivalency certificate	21	70
OUI permit	30 days total time	
GROU equivalency certificate	To be determined	To be determined
GROU permit	30 days total time	
URMULE presubmission	97 days total time	
URMULE standard chemical	247 days total time	
URMULE – microbial, SCLP**, NSCLP***, reduced-risk****, other biopesticides	217 days total time	
URMULE joint review	negotiated	
Master copy	7 verification	42 screen and review
Private label	7 verification	10 screen and review
Registration renewal	Complete by March 15th	
Discontinuation	7 verification	45 screen and review

* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes: time when a submission is "on-hold" pending the applicant.

** Straight Chain Lepidopteran Pheromone

*** Non Straight Chain Lepidopteran Pheromone

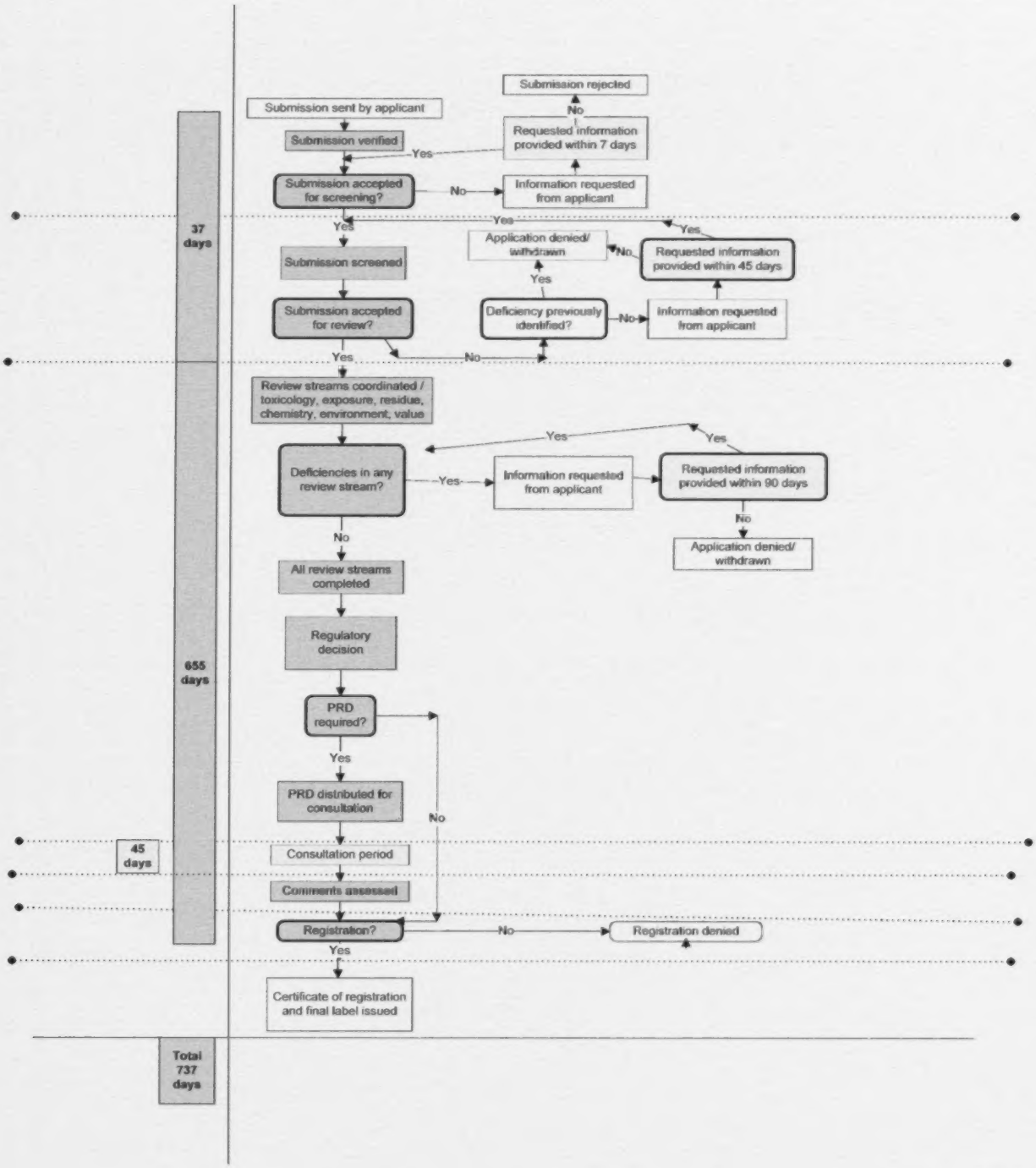
**** Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*

Table 5 Category E Submission Performance Timelines in Number of Calendar Days (for research authorisations and research notification)

Category Subdivision	Completeness Check Time in Days	Review Time in Days*
New technical grade active ingredient (food and non-food use)	21	159
New use	21	69
Notification of research	30 days total	

* Review Time = the time after the end of the completeness check to the final regulatory decision. The review time excludes: time when a submission is "on-hold" pending the applicant.

Appendix II Submission Process Using Category A as an Example



Appendix III Comments Received on Regulatory Proposal; PRO2010-05

Comments were received from five industry stakeholders, including consolidated comments from representative groups.

1.0 Summary of General Comments Supportive of the Revised MOSP

- Two industry stakeholders commented that changes to the Completeness Check timelines were beneficial.
- Three industry stakeholders expressed support for the submission of bilingual labels at application with amendments translated by the PMRA.
- All five industry stakeholders expressed agreement with the changes to the process for deficiencies.

2.0 Summary of Comments Outside the Scope of the Revised MOSP

The objective of the current revision to the MOSP is to consolidate submission timelines in one document, to revise the processes for managing applications to gain efficiencies, and to define performance measures.

- One industry stakeholder commented that the PMRA should take steps to shorten publication timelines

  Response: At this time it is not feasible for the PMRA to shorten the publication stage. The PMRA is required to meet the requirements of the *Official Languages Act* and Treasury Board standards for web-based documentation.

- Three industry stakeholders requested that notification timelines be included in the Revised MOSP.

  Response: The MOSP Regulatory Directive will undergo periodic review in the future, and will continue to consolidate into one document new initiatives.

- Two industry stakeholders requested that low-risk, non-conventional timelines should be added.

  Response: The current timelines for reduced-risk and other biopesticides apply to low-risk non-conventional pest control products.

- Three industry stakeholders commented that the PMRA should reduce timelines for Category B and Category C submissions or reclassify some submission types to those with shorter performance timelines. One industry stakeholder further suggested that the PMRA align submission categories and timelines with the United States Environmental Protection Agency.

  Response: The objective of the current revision to the MOSP is to consolidate current submission timelines in one document, to revise the processes for managing applications to gain efficiencies, and to define performance measures. Changes to the timelines of submissions or to submission classification is outside the scope of this current revision to the MOSP, but will be considered in the future.

- One industry stakeholder commented that changes to MOSP should be done together with cost recovery changes.

  Response: A cost recovery review is ongoing as a separate exercise.

3.0 Summary of Comments Received Expressing Concern about the Revised MOSP

- **Performance measures**: Three industry stakeholders commented that there is need for further justification and analysis prior to changing performance measures from 90% to 85%.

  Response: The PMRA has maintained the performance measure at 90% in this Regulatory Directive.

- **Renegotiation of timelines**: One industry stakeholder commented that they had concern that major deficiencies may arise very late in the review leading to renegotiation of review timelines.

  Response: The ability to renegotiate timelines is intended to allow for more time to review additional data requirements which may be identified if a submission is reclassified or to allow more time as a result of deficiencies that arise late in the evaluation.

  Under PRO96-01 a Notice of Deficiencies is sent following a preliminary data review. If further deficiencies are found during the science review, the review continues with deficient data until it is addressed at the end of the evaluation. This then triggers the second screen (45 days) and the second review (180 days).

Under the Revised MOSP the second screen and second review have been removed. It is expected that there will be fewer evaluation deficiencies late in the review stage since review deficiencies can be addressed at any time during the science evaluation allowing the review to continue with all the required information. Should evaluation deficiencies be identified late in the review stage the renegotiation allows for additional time needed to examine the additional information prior to making a regulatory decision effectively replacing the second screen and second review that can occur under PRO96-01.

- **Label review**: Five industry stakeholders expressed concerns regarding the applicant's ability to make representations on any label amendments before a decision is reached. One industry stakeholder further commented that milestones for communicating label amendments should be included in the Revised MOSP. Two industry stakeholders requested that there be a process early in the review to communicate and allow discussions on changes to the label. Another suggested that there be a mechanism for label changes to occur after the certificate is issued.

  Response: Refer to Section 5.2.2 Label Review. Any label changes after a certificate is issued, other than those permitted via notification and non-notification, require an application.

4.0 Summary of Comments Received Related to MOSP Processes:

4.1 Deficiencies:

- Two industry stakeholders asked if the review clock starts as soon as the PMRA receives a response to a Notice of Deficiencies.

  Response: For all review deficiencies the clock starts as soon as a complete response is received addressing all deficiencies.

- One industry stakeholder commented that the PMRA should define in the Revised MOSP under which conditions the PMRA will continue to review a submission while it is placed "on-hold". Another industry stakeholder recommended that there be a strong internal system to ensure that the science review streams communicate updates to data or information submitted with deficiency responses to ensure that submissions continue to progress while "on-hold".

  Response: Science review streams will continue to actively work on the submission during an "on-hold" time if this is possible and determined to be efficient. This will be handled on a case-by-case basis facilitated by communication between the science review streams concerning the Notice of Deficiencies and updates on new data submitted.

- Two industry stakeholders asked if there is leeway for the deadlines to respond to a Notice of Deficiencies or to respond to a clarification.

Response: As has been current practice, the PMRA will continue to consider extension requests on a case by case basis.

4.2 Label Review Processes:

- Two industry stakeholders requested the PMRA define "significant label changes".

  Response: "Significant label changes" has been changed to "label changes" in this directive. The PMRA will notify the applicant and allow time for representations for all label changes prior to making a final decision.

- One industry stakeholder asked if bilingual labels at application will expedite the registration process.

  Response: While the overall timeline is not reduced in the Revised MOSP, submission of bilingual proposed product labels with the application will reduce the total time from application to decision because there will no longer be a label "on-hold" period at the end of the review requesting the bilingual label.

- One industry stakeholder asked that the PMRA clarify at which stage for minor-use submissions the bilingual label is required.

  Response: Bilingual labels are required upfront when the registrant makes an application to amend the label.

4.3 Grouping of Related Submissions:

- Three industry stakeholders expressed concern over grouping of related submissions. Two industry stakeholders also stated the applicant should be informed and consulted and one industry stakeholder suggested the grouping should adopt the shortest timeline of the group of submissions.

  Response: The grouping of related submissions occurs when one submission depends upon the review decision of the other. For example an end-use product cannot be registered before the technical active ingredient is registered.

4.4 Public Documents:

- Two industry stakeholders noted that no timeline was specified for when the final regulatory decision document must be published relative to the completion of the consultation.

Response: The time allotted for the PMRA to make a regulatory decision following consultation is included within the performance timeline of the submission. The PMRA conducts the public consultation prior to making a regulatory decision. As part of the review process, time to evaluate comments on the consultation is part of the review timeline. Regulatory decision documents are published on the Health Canada Website as soon as reasonably practical once the regulatory decision has been made, which is in compliance with the transparency provisions of the *Pest Control Products Act*.

- One industry stakeholder suggested that the PMRA should consider shortening the review timeline by the 15 days if no decision documents are required.

  Response: For most submission types, 15 days were removed from the screening timeline and added to the review timeline to allow for more time to prepare data and documentation required to be placed in the Register in compliance with Section 42 of the *Pest Control Products Act*. These transparency requirements are not limited to the publication of decision documents; rather they apply to all submission types. For example Section 42, *Pest Control Products Act*, requires the PMRA to place all test data, evaluation reports, and additional information used in the Register. All the information in the Register must be made accessible to the public unless it is confidential business information.

  These transparency requirements did not exist when the original 1996 MOSP timelines were established. The 15 days were removed from screening rather than increasing the total performance measure timeline.

- One industry stakeholder asked that the PMRA include a timeline commitment for the publication of Proposed Maximum Residue Limit documents (PMRLs).

  Response: The processes regarding the publication of PMRLs do not fall under the scope of the Revised MOSP.

5.0 Summary of General Comments

- One industry stakeholder asked why emergency registration submissions are Category B submissions and stated that the timeline is too long. They also asked if emergency registration submissions are for new actives.

  Response: As per the Regulatory Directive, DIR2001-05, emergency uses are given to active ingredients registered in Canada. Emergency applications are given priority and are completed as soon as possible.

- Three industry stakeholders commented on the absence of "Streamline Category C" submissions in the Revised MOSP or requested more clarification regarding "Streamline Category B".

  Response: The change is only to rename "Streamline Category C" as "Streamline Category B". These are submissions described in Regulatory Note REG2002-04, *Category C Submissions Efficacy Reviews*. There are no changes to the criteria, only to the label as Category B submissions to reflect that these types of applications encompass a data review component.

- One industry stakeholder requested a more complete bilingual labeling lexicon to aid in conformity with the PMRA standards.

  Response: This comment has been forwarded to the PMRA's Publication Section for consideration as administrators of the bilingual labeling lexicon.

- One industry stakeholder asked that the PMRA clarify the acceptability of text labels and another requested a more effective mechanism of combining multiple registrations on the same label.

  Response: Label requirements are specified through the Label Process Series of documents; however, following successful pilots over several years using text based labels in Word format the PMRA will accept text based labels in Word format.

- One industry stakeholder asked why PMRA levels (A through I) are not included in the Revised MOSP.

  Response: Level A and B are combined into Completeness Check, and Levels C through I make up the review. In order to manage the process changes of the Revised MOSP the PMRA will use internal review milestones rather than levels in order to avoid confusion with the processes under PRO96-01.

- One industry stakeholder asked if Level C screening will still be done.

  Response: Under PRO96-01, Level C is an internal PMRA timeline for completing a preliminary review. This is used to identify data deficiencies before moving to the next level of review. Under the Revised MOSP a preliminary review will still be performed; however, it is a milestone rather than a level and the submission will continue to progress in review.

  Under the Revised MOSP, a second preliminary review will no longer occur following a review deficiency; rather the review clock will continue from where it went "on-hold".

- One industry stakeholder asked if late submissions will continue to be tracked.

  Response: All submissions are tracked and reported.

- One industry stakeholder commented that it would be preferable to send notices to applicants by email rather than by fax.

  Response: This comment has been forwarded to the PMRA's Registration Directorate for consideration.

- One industry stakeholder asked for guidance or a process to make requests for an expedited review.

  Response: Applications are typically reviewed in chronological order within each MOSP category subdivision. However, under certain circumstances, an expedited review may be considered if there is a critical need. The intent of expedited reviews is to meet urgent needs of users of pest control product or to facilitate risk reduction. This is normally initiated by the PMRA or by pest control product users

- There were several comments on the formatting of appendices of PRO2010-05 that are no longer relevant as comparison with PRO96-01 has been removed.

- There were questions regarding the transition phase to the Revised MOSP. Implementation is specified in Section 2 of this document.